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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,786	12/18/2000	Eiji Hayakawa	2500.5	4015
5514	7590	08/06/2004	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			VENKAT, JYOTHSNA A	
		ART UNIT	PAPER NUMBER	
		1615		

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/647,786	HAYAKAWA ET AL.	
Examiner	Art Unit		
JYOTHSNA A VENKAT	1615		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 23 February 2004.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-7,9-11,13-15,18 and 19 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-7,9-11,13-15,18 and 19 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this **National Stage** application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.  
\_\_\_\_\_

## DETAILED ACTION

The examiner of this application is changed from Amy Pulliam to **Jyothsna Venkat**.

**Receipt is acknowledged** of remarks filed on 2/23/04. Claims 1-7, 9-11, 13-15 and 18-19 are pending in the application and the status of the application is as follows:

### *Specification*

1. The disclosure is objected to because of the following informalities: the specification defines method and tablet according to “ claims” through out the specification.. When the claims are allowed, the claims that may be allowed may not be the same to that recited in the specification.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10, 11, 13-14 and 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is new matter rejection.**

4. The amendment dated 6/20/03 amended claims to add the limitation “ lubricant **substantially only** on surface” and the current amendment changed from “ surface “ to **surfaces”**.

**5. In accordance with MPEP 714.04 applicants should point out support for any amendments made to the disclosure.**

6. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What is meant by “the shape of the tablet is anomalous”? The expression is ambiguous and the metes and bounds of this expression cannot be determined from the disclosure.

The obviousness-type double patenting rejection between the instant claims and the claims over U. S. Patent 6,432,534 is withdrawn solely on the limitation that the instant claims recite” that the molding material not containing the lubricant” and the lubricant is between 0.001-0.2%.

The rejection of claims 10-11 and 19 is also withdrawn since the patent does not disclose the step “mixing said powdered or granular material with diluting agent to make a molding material, said molding material not containing said lubricant”.

***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a **terminal disclaimer**. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9-11, 13-15 and 18-19 are rejected under the judicially created **doctrine of obviousness**-type double patenting as being unpatentable over claims 1-3, and 6-7 of U. S. 6,764,695. An obviousness-type double patenting rejection is appropriate where the **conflicting claims** are not identical, but an examined application is not patentably distinct from the **reference claim(s)** because the examined claim is either anticipated by, or would have been **obvious over**, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ 2d 1226(Fed. Cir. 1998); *In re Goodman*, 11 F. 3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they **are not patentable** distinct from each other because claim 1 is generic to all that is recited in **claims 2 and 4** of the patent. Claim 1 of the patent falls within the genus of claims 1-4 of the application. The patent claims acetyl salicylic acid as the active substance, whereas the instant application recites active compound, which is denaturalized or inactivated when compressed at a pressure **greater than** or equal to 1 ton/cm<sup>2</sup>. The specification at table 3 discloses aspirin. Even though **the claims of the patent** do not have the limitation that the active substance which is denaturalized **or inactivated** when compressed at a pressure greater than or equal to 1 ton/cm<sup>2</sup>, it is the **examiners** position that both are the same. Both the methods do not have lubricant.

Claims 1-7, 9-11, 13-15 and 18-19 directed to an invention not patentably **distinct from** claims 1-3, and 6-7 of commonly assigned U. S. Patent 6,764,695. Specifically, for the **reasons** stated above.

The U.S. Patent and Trademark Office normally will not institute an **interference between** applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U. S. Patent 6,764,695 discussed above, would form the basis for a **rejection**

of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as **prior art** under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve **this issue**, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that **the** conflicting inventions were commonly owned at the time the invention in this application **was** made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

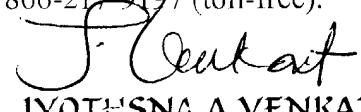
A showing that the inventions were commonly owned at the time the invention in **this** application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the **commonly** assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

**8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A VENKAT whose telephone number is **571-272-0607**. The examiner can normally be reached on Monday-Thursday, 9:30-7:30:1st and 2nd Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the **Patent Application** Information Retrieval (PAIR) system. Status information for published **applications** may be obtained from either Private PAIR or Public PAIR. Status information for **unpublished** applications is available through Private PAIR only. For more information about the **PAIR** system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the **Private PAIR** system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JYOTHSNA A VENKAT  
Primary Examiner  
Art Unit 1615

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